Remarks

Claims 1 to 19 were pending. By this Amendment, claims 1, 9, and 14 to 19 have been amended to limit the claims to pharmaceutical compositions comprising crystalline telmisartan sodium salt. As no new matter has been added thereby, entry of the amendments is respectfully requested. Claims 1 to 19, as amended, are now pending.

The Examiner rejected claims 1 to 19 as allegedly anticipated under 35 U.S.C. § 102(a) over Reidel *et al.* (U.S. Patent App. Pub. No. 2004/0259925).

In response, applicant respectfully traverses the rejection and maintains that Reidel *et al.* is not a proper reference under 35 U.S.C. § 102(a). The subject matter discussed in the Office Action was not present in Reidel *et al.* in the priority documents German Application No. DE 10301371.7, filed January 16, 2003, and U.S. Provisional Application No. 60/446,695, filed February 11, 2003. Accordingly, such subject matter does not predate the priority of the instant application, which claims priority to U.S. Serial No. 60/471,675, filed May 19, 2003, and German Application No. 10319450.9, filed April 30, 2003. Applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

The Examiner also rejected claims 1 to 19 as allegedly unpatentable under 35 U.S.C. § 103(a) over Nakatani *et al.* (U.S. Patent App. Pub. No. 2004/010813) in view of Donsbach *et al.* (U.S. Patent App. Pub. No. 2003/0130331) and Lacourciere *et al.* (American J. Therapeutics 2002, 9(2), page 111-7).

Applicant respectfully traverses the rejection. A *prima facie* case of obviousness generally requires the satisfaction of three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. *See* M.P.E.P. § 2143.

None of Nakatani *et al.*, Donsbach *et al.*, or Lacourciere *et al.* discloses or suggests pharmaceutical compositions of the crystalline sodium salt of telmisartan as required in the

instant amended claims. Accordingly, there is not a suggestion or motivation in the references or in the knowledge generally available to one of ordinary skill in the art, to obtain pharmaceutical compositions of the crystalline sodium salt of telmisartan, much less with a reasonable expectation of success. In addition, the references, alone or in combination do not teach or suggest all of the claim limitations of the instant amended claims. It should be mentioned that the commercial MICARDIS® (telmisartan sodium) product contains amorphous telmisartan obtained by spray drying. Nakatani *et al.*, for example, mentions that crystallinity is not of importance, since amorphous telmisartan sodium is obtained by spray drying. Similarly, Donsbach *et al.* seems to intends to improve the preparation of a pharmaceutical composition comprising spray dried (amorphous) telmisartan by providing a compound which is better soluble than the free base of telmisartan. Thus, Nakatani *et al.* and Donsbach *et al.* teach away from preparing pharmaceutical compositions comprising a crystalline sodium salt of telmisartan, since it is seen as unnecessary and not produced by the spray drying method. Furthermore, Lacourciere *et al.* does not provide what Nakatani *et al.* and Donsbach *et al.* lacks, since it focuses on the use of telmisartan with hydrochlorothiazide, and does not mention a crystalline sodium salt of telmisartan. Applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

Applicant submits that all the pending claims are allowable and respectfully solicits a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Respectfully submitted,

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